

If you fail to promptly correct the Level 1 deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
and
- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

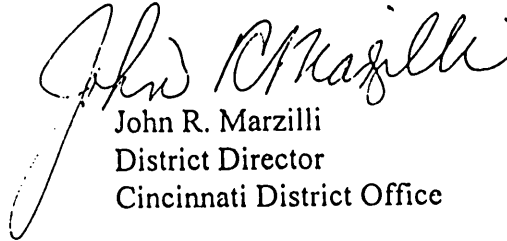
If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513)684-3501, extension 138.

Sincerely yours,



John R. Marzilli
District Director
Cincinnati District Office

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RTBolen